DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 13, 2015

Infix Medical, LLC
Mr. James Holley
Chief Operating Officer
69 Baybridge Drive, Suite M
Gulf Breeze, Florida 32561

Re: K142057
Trade/Device Name: Infix Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 21, 2014
Received: November 21, 2014

Dear Mr. Holley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INFIX

Traditional 510(k) Premarket Notification

Indications for Use

510(k) Number (if known):____K142057_____

Device Name: InFix Cannulated Screw System

Indications for Use:

InFix Cannulated Screw System is generally intended for fracture fixation of various bones and bone fragments, such as femoral neck, intercondylar femoral, malleolus, pilon tibial, calcaneus, talus, tibial plateau, tarsal, metatarsal, wrist, metacarpal, carpal, scaphoid and radius fracture. InFix Cannulated Screw System is also intended for fixation arthrodesis, iliosacral dislocations, and hallux valgus corrections.

Accessories implants:

The round washer is used to increase bone contact area for distributing the forces/load and prevent the screw head from sinking into the bone.

Prescription Use__X__ **AND/OR** **Over-The-Counter Use____**

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number:___K142057_____

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510(k) Summary

Submitter's Name: Infix Medical, LLC
Address: 69 Baybridge Dr. Gulf Breeze, FL 32561
Tel: 850-324-7675 Fax: 855-228-1339

Contact Name: James C Holley

Preparation date: January, 5, 2015

Registration Number: 3010759323

Device Name: InFix Cannulated Screw System

Common Name: Bone Fixation Screws

Classification Name: Class II, as per Title 21 of the Code of Federal Regulations, Sec. 888.3040 Smooth or threaded metallic bone fixation fastener

Product Code: HWC

Predicate Device Information:
SYNTHES 7.0/7.3 MM CANNULATED SCREWS (K962011)
SYNTHES 6.5 MM CANNULATED SCREWS (K021932)
SYNTHES STERILE 4.5 MM CANNULATED SCREWS (K963172)
SYNTHES STERILE 3.5 MM AND 4.0 MM CANNULATED SCREWS (K963192)
SYNTHES STERILE 3.0 MM CANNULATED SCREW AND THREADED WASHER (K962823)
SYNTHES 2.4 MM CANNULATED SCREW (K012945)
ORTHO SOLUTIONS EXTREMITY FIXATION IMPLANTS FOR OSTEOSYSNTHESIS (K111678)

Device Description:
The InFix Cannulated Screw System includes eight cannulated screw specifications and associated washers, which are manufactured from stainless steel and titanium alloy. The cannulated screw is a self-tapping and self-drilling screw with a cancellous thread that can

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be guided into a position via a guided wire. They are used to aid in the alignment and stabilization of fractures to the skeletal system.

Indication for use:

InFix Cannulated Screw System is generally intended for fracture fixation of various bones and bone fragments, such as femoral neck, intercondylar femoral, malleolus, pilon tibial, calcaneus, talus, tibial plateau, tarsal, metatarsal, wrist, metacarpal, carpal, scaphoid and radius fracture. InFix Cannulated Screw System is also intended for fixation arthrodesis, iliosacral dislocations, and hallux valgus corrections.

Accessories implants:

The round washer is used to increase bone contact area for distributing the forces/load and prevent the screw head from sinking into the bone.

Technological Characteristics

The technological characteristic of the InFix Cannulated Screw System are similar to the predicate devices including design, dimensions, and materials. The InFix Cannulated Screw System screws and washers are fabricated from stainless steel 316L per ASTM F138 and Ti-6Al-4V alloy per ASTM F136. The stainless steel 316L and Ti-6Al-4V are commonly used material in orthopedic implants.

Summary of Substantial Equivalence:

The InFix Cannulated Screw System is substantially equivalent to the predicated devices. No new issues of safety or efficacy have been raised.

Summary of Performance Data (Nonclinical and/or Clinical)

Non-Clinical Tests

- Biomechanical Test

  The biomechanical tests ASTM F543 were performed to determine substantial equivalence of the InFix Cannulated Screw System including self-tapping, torsional, axial pullout and driving torque. Results indicate that the subject screws are substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.
- Cleaning Validation

  The cleaning validation was performed in according with the AAMI TIR30:2011 guidance document. The test result shows that the acceptance criteria is met.
- Sterilization Validation

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The sterilization validation was performed in according with the ANSI/AAMI/ISO 17665-1. The test result shows that the acceptance criteria is met.

- The InFix Cannulated Screw System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the InFix Cannulated Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Clinical Tests

Clinical data and conclusions were not needed for these devices to show substantial equivalence.

Conclusions

The InFix Cannulated Screw System has been shown to be substantially equivalent the predicate devices. Result of preclinical tests/engineering justification and the similarities with legal marketed predicated devices indicate the device will perform within the intended use and no new issues of safety or effectiveness have been raised